

REMARKS

Status of the Claims

Applicants appreciate the Examiner's careful review of the independent and dependent claims in the outstanding Office Action. Claims 1, 3-8, 20, 21, and 23-34 are pending in this application, with claims 1, 20, and 29 being independent claims. No amendments are made herein. The Examiner states that claim 8 is withdrawn from consideration, and all remaining claims stand rejected under 35 USC §103(a).

Introduction

The invention claimed herein relates generally to suture welding systems and methods where a device for grasping sutures is provided with two electrodes connected to a source of electrosurgical energy so that the electrosurgical energy, generally radio frequency energy, can be passed through the sutures to weld them together. This application has been pending since December 18, 2001; during its pendency, there have been

- two restriction requirements (3/5/04, 11/28/05);
- two Examiners;
- six office actions (3/5/04, 11/2/04, 4/12/05, 3/16/06, 6/9/06, and 1/4/07) and an advisory action (1/26/05) rejecting all of the claims over prior art; and
- a telephonic interview.

All of this activity has taken place in this application despite the fact that no Examiner in any office action has cited any reference that provides electrodes connected to a source of electrosurgical energy to provide radio frequency energy to the sutures to weld them.

This lack of a basic teaching of the elements of the present invention continues in the outstanding office action in which, once again, the Examiner continues to apply a primary reference that lacks the basic features of the invention.

Rejection of Claims 1, 3-7, 20, 21, and 23-34 Under 35 U.S.C. 103(a)

The Examiner states that claims 1, 3-7, 20, 21, and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,409,743 (Fenton, Jr.) in view of U.S. 6,010,516 (Hulka). Specifically, the Examiner states:

As to claims 1, 3-7 and 27-34, Fenton teaches a welding device for fixedly attaching a first and second lengths of suture teaches a first and second lengths of suture **13**, which can be made from polydioxanone (col. 6, line 63); the device comprising:

- a working end **26**, which is configured to provide a variable gap (adjustable jaws) between an open position or a closed position;

- an energy source or horn **25** connected to a working end **26**;

- a suture contacting element, or collar **1**, located/disposed on the working end during use and having the sutures located therein; wherein the collar is formed from weldable material (col. 6, lines 34-43) and is configured to act as a pod to prevent the sutures from sliding off the working end (Fig. 8A);

- wherein the provision of energy from horn **25** to the working end of the device and into the collar **1**, causes the suture to fuse together (col. 7, lines 3-11).

The main embodiments of the Fenton reference are directed toward the working end being a heating element or an ultrasonic horn. However, Fenton does recite that other well-known techniques, such as optical energy, electrical or RF, can be used to weld the sutures together (col. 4, lines 43-51). Fenton is merely silent with regards to the details of said other known techniques.

On the other hand, Hulka teaches a well known coaptation clamp device that uses RF technology, wherein the device comprises an electrosurgical energy source **12** configured to generate radio frequency waves, and electrodes **22**, which is necessary for completing the bipolar circuit. That is, one electrode would inherently provide the RF energy while the other electrode would inherently return the RF energy in order for the current to flow. Hulka also teaches an RF device that is configured to provide a variable gap that can be selectively adjustable between an open and closed position, and wherein the RF device has a pod in any of the serrated portion shown in Fig. 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

device of Fenton to include the RF technology taught by Hulka since the Fenton reference itself teaches that the device would work with RF technology and that Hulka is merely being provided to teach a generally well known RF device and its associated structures.

Furthermore, the modification to the device of Fenton would have the working end or jaws **26** act as the electrodes, as taught by Hulka, which would in turn have the suture contacting element or collar **1** be disposed on the jaws **26**.

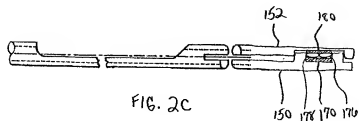
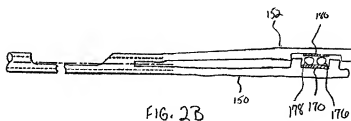
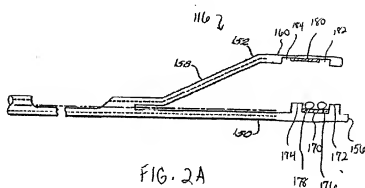
As for claims 20, 21 and 23-26, the above modification of Fenton also discloses a method of welding a first length of suture and a second length of suture, wherein the modified device is provided; a first and second length of suture is placed into the suture contacting element or collar **1**; and an electrosurgical energy source that provides energy to secure the two loose strands of suture **13** together. Furthermore, as shown in the rejection to the device claims above, the suture welding device can be selectively adjustable between an open position and a closed position. Moreover, the collar **1** serves as a pod to prevent the suture from sliding off the working end.

As previously noted by the Applicants, Fenton is another in the line of ultrasonic welding references (all assigned on their face to Axya Medical) cited in this case (see, for example, U.S. Patent No. 6,358,271 to Egan that has been cited in previous office actions, and also page 1, lines 18 to 27 of the present application where ultrasonic welding is discussed in the background).

As an initial matter, Fenton does not relate to disposing lengths of suture on a suture contacting end of a welding system as expressly recited in claim 1. Rather Fenton relates to a "fusible collar for securing sutures without knots and for securing living tissue structures together without sutures." [See Abstract] *Every embodiment* disclosed in Fenton includes this fusible collar, every claim in Fenton recites this fusible collar, and the invention in Fenton is expressly described as residing in the collar. The presently claimed invention works differently.

Claim 1 recites, *inter alia*, first and second lengths of suture and a suture welding device including a *suture contacting element having the first and second lengths of suture disposed thereon*. A *first electrode* is disposed on the suture contacting element *for providing radio frequency energy to the first and second lengths of suture*. This configuration is described in the specification where a suture welding system of the invention includes an electrosurgical energy source and a suture welding device. The suture welding device has a working end as

shown in FIGS. 2A-2C (reproduced below), a suture contacting element disposed on the working end, a first electrode 170 electrically coupled to the electrosurgical energy source, and a second electrode 180 electrically coupled to the electrosurgical energy source. The first electrode 170 is disposed on the suture contacting element for providing electrical energy to the first and second lengths of suture, and the second electrode 180 is disposable proximate to the suture welding site for providing a return electrical energy path to the electrosurgical energy source. When electrical energy is provided by the first electrode to the first and second lengths of suture, the first and second lengths of suture are welded into a fixed attachment.



In use, the suture grasper 116 is moved from an open position (FIG. 2A), to an intermediate position (FIG. 2B), and finally to a closed position (FIG. 2C). When the suture grasper 116 is fully closed and two lengths of suture 176, 178 are tightly held within the grasper 116, the lengths of suture 176, 178 can be deformed due to pressure applied to them by the electrodes 170, 180. With the first and second lengths of suture placed into contact with the suture contacting element, electrical energy from the electrosurgical energy source is provided through the first electrode to the first and second lengths of suture to weld the first length of suture to the second length of suture to create a fixed attachment therebetween.

In contrast, Fenton only discloses sutures that are wrapped in a fusible collar for loading into an ultrasonic welding device. The Examiner asserts that “the collar 1 is being interpreted as the suture contacting element, which is disposed on the working end 26 during use.” However, as explained at col. 4, lines 30-33 of Fenton, the collar (1) is entirely separate from the fusing tool (20) that is used to compress and fuse the collar (1) around the sutures. Independent claim 1, on the other hand, require a *suture contacting element* that is *located on the working end* of a suture welding device *with the first and second lengths of suture disposed thereon*. As explained at pg. 5, lines 21-24 of the present application, the suture welding device claimed by Applicants includes a proximal handle and “a distal extender tube 16 having a suture grasper or suture contacting element 18 on its distal or working end 20.” Thus, the collar (1) cannot be a “suture contacting element” as recited in claim 1 because the collar (1) is not part of the fusing tool (20). Moreover, the fusing tool (20) taught by Fenton does not include a “suture contacting element,” only “collar contacting elements.” The sutures disclosed in Fenton are never disposed on the end effector (24), only the collar (1) is.

Claim 1 further recites that the first electrode is disposed on the suture contacting element to provide radio frequency energy to the first and second lengths of suture. *Fenton does not disclose*, teach or suggest putting any type of *energy delivery apparatus on the fusible collar* – as it must according to the rejection outlined in the Office Action because the suture contacting element is the fusible collar according to the Examiner and claim 1 requires the first electrode to be on the suture contacting element.

The differences between Fenton and the present claims in this regard is further highlighted by claim 3, which depends directly from claim 1. In claim 3, the suture contacting element comprises two opposing faces having a variable gap therebetween, with each face having an electrode disposed thereon. *The fusible collar of Fenton does not have two opposing faces with a variable gap therebetween, and an electrode disposed on each face of the fusible collar.* There is no way to make the Examiner's proposed reading of the prior art disclose, teach or suggest the elements of claims 1 and 3, *the analogy of the fusible collar to the suture contacting elements does not hold up.*

The Examiner further asserts that Applicants' arguments regarding the fact that Fenton fails to teach the application of RF energy to weld sutures are not persuasive because:

Fenton does disclose that the device is capable of not only fusing the collar, but is also able to fuse the suture together without fusing the collar to the suture (col. 7, lines 3-11).

The passage cited by the Examiner, col. 7, lines 3-11, merely states that the collar and sutures can be made from materials with different melting points to allow the bonds to occur at various interfaces. This passage, nor any other passage of Fenton, says that other well-known techniques can be used to weld the sutures together. Rather, Fenton says that these techniques can be applied to collars – not to sutures. The actual passages from Fenton that discuss RF energy are as follows:

The overlapping portions of the collar are adapted to fuse to each other around the elongated members upon ***application of sufficient energy to the overlapping portions of the collar.*** . . . The energy may be generated from a variety of sources known in the art, such as for example, thermal energy, optical energy, radio-frequency energy, current sources or more preferably, ultrasonic energy. [Column 2, lines 15-39.]

Various methods of fusing or joining sutures or other elongated structures together ***joining by the application of energy to the fusible collar are well known in the art and can be employed to secure the band and sutures.*** Examples of such techniques include, but are not limited to, thermal energy (e.g., heat), optical energy (e.g. laser), electrical (e.g.,

radiofrequency RF), current sources (e.g., resistive heating), and preferably, ultrasonic energy. [Column 4, lines 43-51.]

The **collar material is preferably also capable of being fused or joined together upon the application of energy**, such as thermal energy (heat), optical energy (laser generated), electrical energy (radio frequency, RF), current sources (resistive heating) or, preferably, ultrasonic energy, to the collar. [Column 6, lines 36-39.]

In each case, *Fenton only talks about applying energy to the collar – never to the suture* as is required by the present claims.

Hulka does not teach or suggest these claim recitations. Hulka, which provides a coaptation clamp device delivers RF energy only to tissue as is well known and as been recognized in numerous patents cited in the prosecution of the present application. No portion of the Hulka device contacts sutures, sutures are never disposed on the device, and RF energy is not delivered to sutures. Accordingly, neither reference, alone or combined, teaches or suggests the recitations of claim 1.

In addition, there is no teaching or suggestion to combine these references and the Examiner provides no motivation to do so (the Examiner merely states that Fenton teaches that the device would work with different types of energy – which it does not unless a collar is used). Hulka provides energy only to tissue; Fenton provides energy only to a collar – there is no reason why a person of ordinary skill in the art would combine these references. Even if a person of ordinary skill in the art did combine these references, that person would presumably develop a clamp that delivers energy to a collar that surrounds tissue – as is expressly taught by Fenton, for example, in the portions quoted above.

Independent claim 20 is an independent **method claim** that recites the provision of a suture welding device, which, like claim 1, includes a suture contacting element and a first electrode. The method further includes “**placing a first length of suture and a second length of suture into contact with the suture contacting element.**” The suture contacting element of claim 20 includes “**two opposing faces having a variable gap therebetween, each face having an electrode disposed thereon.**” As note above, neither Fenton nor Hulka place a suture into

contact with a suture contacting element on the suture welding device – indeed, the Examiner’s analogy of the fusible collar to the suture contacting element makes the disclosure, teaching or suggesting of this method steps by the cited references quite impossible for the reasons noted above with respect to claims 1 and 3. In particular, the fusible collar does not define a variable gap and have electrodes on opposed faces so that it can deliver radio frequency energy to the sutures. Claim 20 is thus patentable for at least all of the same reasons as claims 1 and 3.

Independent claim 29 includes the suture contacting element and first electrode recitations, and further includes at least one pod on the suture contacting element configured to prevent the first and second sutures from sliding off of the suture contacting element. Claim 29 is patentable over the cited references because the cited references do not include suture contacting elements having electrodes for delivery of energy to the sutures. In addition, neither reference discloses or suggests a pod on the suture contacting element to prevent the sutures from sliding off. The Examiner asserts that “the collar 1 serves as a pod to prevent the suture from sliding off the working end.” As explained above, the Examiner also asserts that the collar (1) is the “suture contacting element.” Independent claim 29 requires both a suture contacting element and a pod – more specifically, a suture contacting element having at least one pod disposed thereon. Thus, it is impossible for the collar (1) to be both the suture contacting element and the pod as these are separate elements of the suture welding device.

Even further, Applicants’ claims 6, 26 and 34 recite first and second lengths of suture that are made of polydioxanone. The Examiner continues to note that Fenton states that sutures can be made of polydioxanone. Applicants will gladly stipulate that polydioxanone sutures are known – but that is not the invention of these claims. By virtue of their dependence from the independent claims, these claims recite polydioxanone sutures that are welded to each other by the delivery of RF energy through the recited suture welding devices. Fenton does not disclose, teach or suggest such welding. Rather, Fenton teaches that any elongate thing (any suture or any tissue) can be joined together by placing a fusible collar around it.

Just because polydioxanone sutures are known does not mean that they can be welded as recited in the claims. In fact, an express goal of the claimed invention, the first suture welding device of its type, is to employ radio frequency waves in order to facilitate the welding of

polydioxanone sutures as the present inventors have found that existing suture welding methods did *not* work with polydioxanone sutures. (See, e.g., the background of the present invention at page 1, lines 22 to 31.) Fenton's approach does not change these facts because Fenton does not weld the sutures, he heats a fusible collar as a substitute.

CONCLUSION

If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

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Respectfully submitted,



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